

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 2005577-0003	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2005/008600	International filing date (<i>day/month/year</i>) 14 March 2005 (14.03.2005)	Priority date (<i>day/month/year</i>) 19 March 2004 (19.03.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant LI, Xiu-Min			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report
19 September 2006 (19.09.2006)

Authorized officer

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PATENT COOPERATION TREATY

REC'D 19 SEP 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

18 SEP 2005

Applicant's or agent's file reference

2005577-0003

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US05/08600

International filing date (day/month/year)

14 March 2005 (14.03.2005)

Priority date (day/month/year)

19 March 2004 (19.03.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 35/78 and US Cl.: 424/725

Applicant

LI, XIU-MIN

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/08600

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/08600

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-14</u>	NO
Industrial applicability (IA)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-14 lack inventive step under PCT Article 33(3) as being unpatentable over Li et al (US 6,630,172). Li et al. teach (see, e.g., claim 2 and column 24, lines 44-51) a composition comprising Ganoderma Lucidum (i.e. Ling-Zhi) and Ku-Shen for the treatment of asthma. Li et al. do not teach a composition of the other active ingredients of Gan-Cao, a corticosteroid and a bronchodilator contained within its composition for the treatment of asthma. SHEU teaches (see, e.g., column 8, lines 27-30) licorice root (i.e. Gan-Cao) for the treatment of asthma. BRIDGES et al. teach (see, e.g., column 1, lines 41-45) bronchodilators for the treatment of asthma. CAI et al. teach (see, e.g. column 1, lines 41-43) corticosteroids for the treatment of asthma. It would have been obvious to one of ordinary skill in the art to modify Li et al's teachings to include the beneficial teachings of Sheu, Bridges et al and Cai et al. because the above combined teachings would create an improved composition for the treatment of asthma and the composition would also inherently suppress GATA-3 in patients and suppress the activation of memory Th2 cells in patients when treating asthma. The adjustments of other conventional working conditions (i.e. the amounts and the vehicle the composition is contained within), is judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 1-14 meet the novelty criteria set out in PCT Article 33(2), because there is no express teachings of a composition comprised of all the claimed active ingredients together or within the claimed ranges.

Claims 1-14 meet the criteria set out in PCT Article 33(4), and thus claims 1-14 have industrial applicability because the subject matter claimed can be made or used industry.